

EXHIBIT M

Priselac, Jessica

From: Priselac, Jessica
Sent: Sunday, November 22, 2020 9:52 AM
To: 'Layne Hilton'
Cc: Conlee Whiteley; 'Adam Slater'; 'Daniel Nigh'; rubhon@gmail.com; David J. Stanoch; 'Valsartan PEC'; Goldberg, Seth A.; Ferretti, Joseph S.; Schwartz, Barbara; Klein, Alan; 'lockardv@gtlaw.com'; 'rubensteinb@gtlaw.com'; 'harkinss@gtlaw.com'; 'CCT@pietragallo.com'; 'JMR@pietragallo.com'; 'Nagle, Brittney <bee.nagle@kirkland.com> (bee.nagle@kirkland.com)'; 'JHeinz@c-wlaw.com'; 'Nakul Y. Shah'; 'Frank H. Stoy'
Subject: RE: In re Valsartan, Losartan and Irbesartan (ZHP Manufacturing Facilities)

Layne,

It is unnecessary to make unfounded accusations against ZHP (and unnecessarily involve every manufacturer defendant) rather than simply request a list of all ZHP subsidiaries in a straightforward manner—we will provide this information to you. ZHP is a public company and it has made no effort to conceal its subsidiaries from Plaintiffs, as you have alleged below. We cannot promise you a complete list by Monday given that today is Sunday, but we will provide you a list next week.

As your request was couched in a number of mischaracterizations, we must clarify:

- There is nothing in the record wherein you requested and/or the court ordered information to be produced about ZHP or ZHP-related facilities that manufacture “intermediaries” and “starting agents”; moreover, if you had we would have vigorously opposed such a request given the inherent ambiguity and overly broad nature of both terms.
- While I was not on the call on Nov. 6, my colleagues that were have told me that you simply asked the question I answered in my original email – whether valsartan products were manufactured somewhere other than Xunqiao or Chuannan. As I’ve previously responded, they are not.
- ZHP has never represented that the corporate organizational chart you have copied below includes all of its subsidiaries, the chart simply shows the relationship between the named parties and their ownership structure, which was Plaintiffs’ focus at the time the document was produced. Of course, Plaintiffs were well aware that the chart did not include all ZHP subsidiaries, as evidenced by the fact that you requested and received documents from a non-party subsidiary that is not on the chart below—Shanghai Syncores.

Finally, and importantly, Plaintiffs’ subtle (and not so subtle) digs regarding our clients’ Chinese nationality over the past several months have not gone unnoticed, and should be stopped.

I hope this ends the back and forth on this subject, and that you refrain from making unfounded accusations about our clients so that the parties can focus on the important issues in this case without spending time on unnecessary sideshows.

Best regards,

Jessica

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From: Layne Hilton <l.hilton@kanner-law.com>

Sent: Friday, November 20, 2020 9:01 PM

To: Priselac, Jessica <JPiselac@duanemorris.com>

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Subject: RE: In re Valsartan, Losartan and Irbesartan (ZHP Manufacturing Facilities)

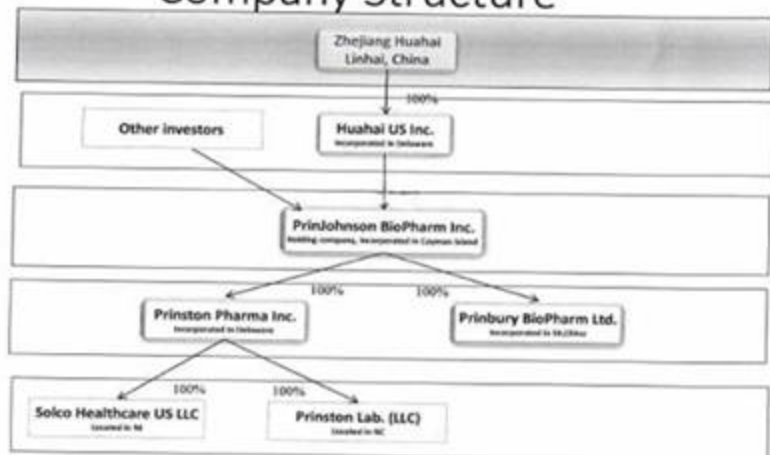
Jessica:

Plaintiffs have made a timely request for this information. On November 6, 2020 during a meet-and-confer with ZHP, Plaintiffs raised the issue of references to additional Valsartan API manufacturing facilities in communications between Torrent and ZHP (that were located in Torrent's custodial production). Hours later, ZHP produced a tranche of thousands of custodial documents, some of which included the first references to these additional manufacturing facilities (and identifying other manufacturing facilities not previously known to Plaintiffs). Plaintiffs formally raised the issue in writing on November 11, 2020.

Plaintiffs cannot be faulted for not previously inquiring about these facilities and/or entities during the 2019 discovery negotiations when **Plaintiffs did not know they existed prior to November 2020**. More than that, during the discovery negotiations, ZHP's affirmative representations regarding corporate structure were **much** different than a sprawling operation of almost 50 corporations. .

For example, on October 22, 2019, a day prior to Plaintiffs' meeting with Mr. Du (which you describe as the time when Plaintiffs should have obtained this information), ZHP produced the attached, which ZHP represented was a corporate organizational chart showing ownership structure. I copy the chart below for reference:

Company Structure



During this “extraordinary access” to Mr. Du, Plaintiffs were met with objections when even asking Mr. Du questions about the “other investors” identified in the above simplistic organizational chart. Plaintiffs could not even get full information regarding the corporate entities that **were** identified by ZHP. How were Plaintiffs supposed to discover information relating to an additional 35+ related corporate entities that were **not** identified by ZHP?

To be clear: Plaintiffs are not engaging in some “rabbit hole” endeavor and/or requesting a sprawling and expanded production of documents. Corporate information regarding wholly-owned subsidiaries and/or facilities related to the manufacture, sale, and distribution of USDMF Valsartan API is unquestionably responsive to the Court-Ordered Request for Production Nos. 1-3. See D.E. 328 at 8. The identity of all related corporate entities that were in the business of selling key starting materials and intermediates used in the manufacture of product sold in the United States is clearly responsive to these requests. It would be nonsensical to argue otherwise. Plaintiffs should not be required to ferret through English language translations of ZHP’s website to obtain this information. Candidly, I could not even access the website link below due to security preferences on my work server due to questionable Chinese website domain activity. Regardless – this corporate information was requested by Plaintiffs through formal discovery, it was ordered by the Court, and it must be produced by ZHP.

Will ZHP agree to produce a list identifying the 40+ entities which are wholly-owned by ZHP (or, in the alternative, a complete organizational chart kept in the ordinary court) by Monday? If not, then Plaintiffs will have to raise this issue with the Court. ZHP’s refusal to provide this information is hampering Plaintiffs’ ability to fully assess the document production of every single Defendant in this litigation.

Best,

Layne

From: Priselac, Jessica <JPriselac@duanemorris.com>

Sent: Friday, November 20, 2020 5:16 PM

To: Layne Hilton <l.hilton@kanner-law.com>

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<rubensteinb@gtlaw.com>; 'harkinss@gtlaw.com' <harkinss@gtlaw.com>; 'CCT@pietragallo.com' <CCT@pietragallo.com>; 'JMR@pietragallo.com' <JMR@pietragallo.com>; 'Nagle, Brittney <bee.nagle@kirkland.com> (bee.nagle@kirkland.com)' <bee.nagle@kirkland.com>; 'JHeinz@c-wlaw.com' <JHeinz@c-wlaw.com>; 'Nakul Y. Shah' <nshah@HillWallack.com>; 'Frank H. Stoy' <FHS@Pietragallo.com>

Subject: RE: In re Valsartan, Losartan and Irbesartan (ZHP Manufacturing Facilities)

Layne,

As an initial matter, the Court previously ordered (at ECF Doc. No. 303) that the only facilities at issue for discovery purposes in this litigation are the facilities that manufactured valsartan API and finished dose products sold in the United States. For ZHP, those facilities are Chuannan and Xunqiao.

The Court's order should end this discussion, but to address your unfounded implication that ZHP has attempted to withhold discoverable information from Plaintiffs, we note that the existence of companies that are either owned or partially owned by ZHP is publicly available information (see, e.g., <http://en.huahaipharm.com/qyjj/index.aspx> (noting that ZHP has more than 40 subsidiaries)), a fact that Plaintiffs have been well-aware of since the inception of this litigation, as evidenced by the fact that Plaintiffs have requested (and received) discovery from both party and non-party affiliates of ZHP. To the extent you had additional questions about ZHP's corporate structure after initiating this litigation, you had ample opportunity to ask them last year when Plaintiffs were given extraordinary access to ZHP's Vice-Chairman for an all-day interview attended by Judge Schneider.

Further, to the extent you appear to be seeking to expand the scope of discovery based on information Plaintiffs have had since last year (such as the DMF you referenced below, which was produced in core discovery), we would vigorously oppose any such expansion. Indeed, the Court has stated that the purpose of core discovery was to prevent the parties from going down the "rabbit hole" you appear to be digging. See Tr. of Apr. 10, 2019 Conference at 31:14-17 ("But we think it's important that you get these core documents. It'll . . . guide your discovery in this case so you don't go down a rabbit hole.").

Best regards,

Jessica

Jessica Priselac
Attorney at Law

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From: Layne Hilton <l.hilton@kanner-law.com>

Sent: Thursday, November 19, 2020 1:01 PM

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Cc: Conlee Whiteley <c.whiteley@kanner-law.com>; 'Adam Slater' <ASlater@mazieslater.com>; 'Daniel Nigh' <dnigh@levinlaw.com>; rubhon@gmail.com; David J. Stanoch <d.stanoch@kanner-law.com>; 'Valsartan PEC' <valpec@kirtlandpackard.com>

Subject: RE: In re Valsartan, Losartan and Irbesartan (ZHP Manufacturing Facilities)

Jessica:

Thank you for your response. However, this does not address Plaintiffs' concern that ZHP has been operating an untold (and undisclosed) number of additional manufacturing facilities that were ostensibly unrelated companies, but were actually part of the larger ZHP corporate umbrella. Additionally, in the intervening days since Plaintiffs first made this request, Plaintiffs have reviewed documents and discovered **two more** previously undisclosed manufacturing facilities. See ZHP00447543 (identifying additional intermediate locations at a facility simply referred to as "Huanan" and "Rudong").

Plaintiffs are entitled to have a complete and accurate understanding of ZHP's larger corporate structure (a request Plaintiffs have been making since October 2019), including any and all subsidiary companies being operated by ZHP. Further, while we appreciate your (narrow and limited) representation as to API and Finished Dose Manufacturing, your response purposefully ignores the issue of starting materials, solvents, or intermediates used in the manufacture of USDMF Valsartan API.

In our initial review of the Drug Master Files produced by ZHP, Plaintiffs noted that ZHP's filing disclosed several entities from which they procured starting materials – including a company called "Linhai Huanan Chemical Co., Ltd." and "Nantong Huayu Chemical Technology Co., Ltd." See PRINSTON00010648. Plaintiffs have now confirmed (from additionally newly produced documents) that the company styled as "Linhai Huanan Chemical Co., Ltd." (which was providing starting materials and intermediates used in the manufacture of USDMF Grade Valsartan for ZHP), **is a wholly owned subsidiary of Zhejiang Huahai**. See ZHP00420067.

The implication of this revelation cannot be overstated. Mylan (MYLAN-MDL2875-00232986), Aurobindo (APL-MDL 2875-0018342) and Hetero (HLL387308) used this vendor for their USDMF Valsartan API Manufacture. More than that, it is obvious that ZHP itself was the entity selling these key starting materials to customers for the manufacture of Valsartan. See ZHP00420067.

Plaintiffs are entitled to complete and accurate information regarding ZHP's larger corporate structure so that Plaintiffs can adequately review not only ZHP's documents, but also the documents for every Defendant who sourced key starting materials and/or intermediates from one of these ZHP wholly-owned subsidiaries. The information Plaintiffs requested last week is as follows:

- Identifying information (including name of the entity) related to all wholly owned subsidiaries within the larger Huahai umbrella, including facilities used to manufacture intermediates and starting materials (including information related to the Nantong, Changxing, Rudong and Huanan sites);
- Whether Nantong Huayu Chemical Technology Co., Ltd. is a wholly owned subsidiary; and
- Whether any of these wholly owned subsidiaries (aside from Nantong Huayu Chemical and Linhai Huanan Chemical) supplied starting materials, reagents, solvents and/or intermediates used in the manufacture of ZHP's USDMF grade Valsartan API.

Unless ZHP is prepared to provide Plaintiffs with this very elemental information by COB Friday (i.e., the names and identifying information of all wholly-owned subsidiaries which manufacture starting materials, intermediates, and/or API), Plaintiffs intend to raise this issue with the Court at next week's CMC.

Best,

Layne

From: Priselac, Jessica <JPriselac@duanemorris.com>

Sent: Wednesday, November 18, 2020 8:00 PM

To: Layne Hilton <l.hilton@kanner-law.com>; Goldberg, Seth A. <SAGoldberg@duanemorris.com>; Ferretti, Joseph S. <JSFerretti@duanemorris.com>; Schwartz, Barbara <BASchwartz@duanemorris.com>; Klein, Alan <AKlein@duanemorris.com>; 'lockardv@gtlaw.com' <lockardv@gtlaw.com>; 'rubensteinb@gtlaw.com' <rubensteinb@gtlaw.com>; 'harkinss@gtlaw.com' <harkinss@gtlaw.com>; 'CCT@pietragallo.com' <CCT@pietragallo.com>; 'JMR@pietragallo.com' <JMR@pietragallo.com>; 'Nagle, Brittney' <bee.nagle@kirkland.com> (<bee.nagle@kirkland.com>); 'JHeinz@c-wlaw.com' <JHeinz@c-wlaw.com>; 'Nakul Y. Shah' <nshah@HillWallack.com>; 'Frank H. Stoy' <FHS@Pietragallo.com>

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Subject: RE: In re Valsartan, Losartan and Irbesartan (ZHP Manufacturing Facilities)

Layne,

We have conferred with our client and confirmed that ZHP has only ever manufactured valsartan API and valsartan finished dose products at the Chuannan and Xunqiao sites.

Best regards,

Jessica

Jessica Priselac

Attorney at Law

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From: Priselac, Jessica

Sent: Monday, November 16, 2020 6:02 PM

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Subject: RE: In re Valsartan, Losartan and Irbesartan (ZHP Manufacturing Facilities)

Layne,

We are in receipt of your email, and are looking into the issues you raised below. We will get back to you later this week.

Best regards,

Jessica

Jessica Prisela

Attorney at Law

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From: Layne Hilton <l.hilton@kanner-law.com>

Sent: Wednesday, November 11, 2020 2:50 PM

To: Goldberg, Seth A. <SAGoldberg@duanemorris.com>; Ferretti, Joseph S. <JSFerretti@duanemorris.com>; Schwartz, Barbara <BASchwartz@duanemorris.com>; Prisela, Jessica <JPrisela@duanemorris.com>; Klein, Alan <AKlein@duanemorris.com>; lockardv@gtlaw.com; 'rubensteinb@gtlaw.com' <rubensteinb@gtlaw.com>; 'harkinss@gtlaw.com' <harkinss@gtlaw.com>; 'CCT@pietragallo.com' <CCT@pietragallo.com>; 'JMR@pietragallo.com' <JMR@pietragallo.com>; 'Nagle, Brittney' <bee.nagle@kirkland.com> (bee.nagle@kirkland.com)' <bee.nagle@kirkland.com>; 'JHeinz@c-wlaw.com' <JHeinz@c-wlaw.com>; 'Nakul Y. Shah' <nshah@HillWallack.com>; 'Frank H. Stoy' <FHS@Pietragallo.com>

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Subject: In re Valsartan, Losartan and Irbesartan (ZHP Manufacturing Facilities)

Counsel:

I write further to an issue I initially raised in the Parties' November 6, 2020, meet-and-confer, related to the issue of ZHP's API manufacturing facilities.

Plaintiffs have reviewed documents produced by Defendant Torrent which include communications between Torrent employee Siddhanand Padukone and Minda Cai regarding ZHP facilities that were US FDA approved to manufacture Valsartan for the US Markets. See TORRENT-MDL2875-00095945. In that email, dated September 27, 2012, Minda Cai indicates that ZHP is aware that API Customers prefer two manufacturing sites for their API suppliers, and states that, as of 2012, ZHP has "already a established a new manufacturing site in Jiangsu province, call[ed] Huahai NanTong pharmaceutical Co., LTD, a fully huahai own[ed] subsidiary which will manufactur[e] Sartans (including Valsartan)....in 2 years. Now the new factory is under design and construction will start next year, it will adopt same GMP and process from current Huahai operation system, and we hope it could be also approved by the US FDA." *Id.* In subsequent internal emails, Torrent discusses this second ZHP Valsartan API manufacture site, noting that ZHP "will have another site in Jiangsu province, which will be operational in 2013-2014 and available for US in 2016 (approximate the same time when our proposed 2nd source would be approved for US)." See Torrent-MDL2875-00096051.

Documents produced on November 6, 2020 are the **first** documents produced by ZHP that even make mention of this additional potential Valsartan US FDA API manufacturing site. See ZHP00419229 (a 2015 presentation made by ZHP to Torrent which refers to a Nantong manufacturing site under construction as of Summer 2015, set to be built on 421,000 square miles of land). In another set of newly provided tranche of presentations, ZHP also refers to an additional Changxing Site, which likewise appeared to manufacture APIs and intermediates. See ZHP00410399 (just one example of 60 presentations which were first produced to Plaintiffs on November 6, 2020). Additional documents also make reference to a Rudong Site. See ZHP00429924. Plaintiffs were previously unaware of *each of these* facilities.

It goes without saying that Plaintiffs are troubled by the representations made by ZHP that the Nantong Site would be used for Valsartan API manufacture. Additionally, because of these communications between ZHP and Torrent, Plaintiffs have also grown concerned that ZHP may potentially have countless other previously-undisclosed wholly owned subsidiary manufacturing sites that have been used in the manufacture or testing of Valsartan (either through the manufacture of KSMs and/or Intermediates), but appeared to Plaintiffs to be to be completely unrelated corporate entity (and not a wholly owned subsidiary of ZHP).

Given the obvious implications such a development would have on discovery, Plaintiffs request that ZHP provide the following information regarding these previously-undisclosed facilities, including:

- any identifying information related to the Nantong and Changxing Site, including any FEI numbers (or other identifying numbers), formal facility names and/or addresses;
- whether either facility was involved in any way in the manufacture of Valsartan API (including in the manufacture of the API or intermediates used in the manufacture of the API, and/or testing);
- any identifying information for any other facilities which are wholly owned by ZHP (and may ostensibly appear to be an unrelated company (such as the aforementioned “Huahai Nantong Pharmaceutical Co.” discussed with Torrent), including any FEI numbers, formal names, and addresses;
- whether any of these wholly owned entities were involved in the manufacture of Valsartan API (including in the manufacture of the API or intermediates used in the manufacture of the API, and/or testing); and
- the current status of each of these entities.

Plaintiffs request this information by Monday November 16, 2020, such that the Parties will have time to confer regarding these previously undisclosed facilities in the week prior to the CMC with the Court.

Best,

Layne

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